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Patent and Trademark Office



16138 U.S. PTO

06-05-03

60475657

PTO/SB/16 (10-01)

APPROV

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PTO

17602 U.S. PTO

60/475657

06/03/03

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.

EV275392544US

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<input type="checkbox"/> Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (500 characters max)					
Colloidal Silver Human Treatment					
Direct all correspondence to: CORRESPONDENCE ADDRESS					
<input checked="" type="checkbox"/> Customer Number		27,966		Place Customer Number Bar Code Label here	
OR		Type Customer Number here			
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Address					
City		State		ZIP	
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ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification		Number of Pages		17	
<input checked="" type="checkbox"/> Exhibit(s)		Number of Sheets		32	
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76		<input type="checkbox"/> CD(s), Number			
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METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT					
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.				FILING FEE AMOUNT (\$)	
<input type="checkbox"/> A check or money order is enclosed to cover the filing fees					
<input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number:		18-0013		\$80.00	
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.					
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
<input checked="" type="checkbox"/> No.					
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: _____					

Respectfully submitted,

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Date 06/03/2003

REGISTRATION NO.

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39,481

40056-0002

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Provisional Application, Commissioner for Patents, Alexandria, VA 22313-1450.

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PROVISIONAL APPLICATION FOR LETTERS PATENT

for

COLLOIDAL SILVER HUMAN TREATMENT

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COLLOIDAL SILVER HUMAN TREATMENT

FIELD OF THE INVENTION

The present invention relates generally to colloidal silver, and more particularly, to a method of using colloidal silver in human applications, including disease prevention, disease cure, and surface disinfecting, among other things.

BACKGROUND

It is well known that silver has germicidal properties. In fact, silver was employed as a germicide and antibiotic before modern antibiotics were developed. In previous centuries, users would shave silver particles into their drinking water, or submerge whole silver pieces in the drinking water, for the purpose of ingesting the silver by drinking the water.

There are many reasons why administering silver suspended in solution would enhance an individual's health. It is possible that such a solution operates to inhibit the growth of bacteria, viruses, and other unwanted organisms, as well as eradicating such existing bacteria, viruses, and other organisms. It is also possible that a solution of silver can have an anti-inflammatory effect, sufficient to reduce symptoms of asthma. Silver in solution might also act in a similar fashion to a homeopathic remedy. These are just a few of the possible reasons why silver in solution, such as colloidal silver, is effective at enhancing health.

Current methods of using and administering silver involve the use of colloidal silver. Although most silver colloids are very similar, the earlier colloids do have some characteristics that make them inferior products and not as effective as possible in treating and curing illnesses and infections. For example, some colloids are unstable, requiring stabilizers to keep the silver

particles suspended in the solution. Other products require the solution to be shaken to produce a dispersed colloid. Still others may require refrigeration, which indicates a presence of other ingredients that may spoil. Although these inferior silver colloids are relatively inexpensive, they are not very efficient and can only achieve a low bioavailability. Many current products lose their suspension over time, and do not effectively kill the bacteria, viruses, or fungi.

Thus, there exists a need to develop a high quality silver colloid, which remains suspended in a colloid, and which can effectively perform its functions with low silver concentrations. There is also a need to develop a silver colloid which will effectively serve to kill bacteria such as MRSA (Methicillin-resistant *Staphylococcus aureus*), Tuberculosis, Anthrax and Malaria.

DETAILED DESCRIPTION OF THE INVENTION

The present invention consists of the use of colloidal silver, for the treatment of bacterial, viral and fungal infections and ailments. The concentration of silver in the solution can be varied, depending on the purpose for which it will be used. It has been known to use colloidal silver for the treatment of the following ailments:

- **Asthma:** It has been suggested by a number of researchers that the new silver solution has important anti-inflammatory properties. This would explain the benefit of the silver solution in the treatment of asthma, which is caused by the inflammation of the bronchial tubes. There is evidence that *S. aureus* can be a cause of asthma. It is also a cause of hard-to-treat skin infections in Japan. A Japanese firm is currently conducting clinical trials on the new silver solution on these skin infections. The silver solution is effective in stopping asthma and asthma attacks.

- **Athletes Foot:** Spray directly on the cleaned infected area and let dry. In addition, saturate a clean sock over the infected area and wear as usual
- **Burns and Cuts:** Spray the 10ppm silver solution directly onto the wound. Leave uncovered and wet for 5-20 minutes per application. Apply one to three times per day, depending on severity. Personal reports suggest that the burns and cuts will heal very rapidly. One little girl had splashed scalding oil on her face and had a large burn area. Her mother sprayed the solution directly on the burn twice daily and left it wet with the solution for 15- 20 minutes. The girl showed an 85%-90% recovery within two weeks. Six months later, there was virtually no visible scarring on the girl.
- **Cankers and Other Mouth Sores:** Take approximately one tablespoon of 10ppm new silver solution and hold it in the affected area of the mouth for at least five minutes. Repeat this two to three times a day. Noticeable improvements within 24 hours have been commonly reported.
- **Cold Sores:** Saturate a cotton ball with 10ppm silver solution and apply to lip. Keep the solution in contact with the sore for 5-20 minutes or more, the longer the better. Repeat two to three times per day. It is most effective at the first sign of a cold sore. Under these conditions, the cold sore may never get to the blister stage, but often disappears in one to three days.
- **Diabetic Neuropathy:** Because of impaired circulation, it is common that for diabetics cuts and scratches heal more slowly. Taking the new silver solution appears to shorten healing time and also to reduce pain in the extremities. The solution should be both taken internally (1-2 tsp per day) and sprayed directly on affected areas two to three times daily.

- **Diaper and Other Rashes:** For diaper rash spray affected area with 10ppm silver solution at each change of diaper. Leave wet and put on new diaper. For other skin irritation and rashes, spray affected area and leave wet for at least five minutes. Repeat two or three times per day. Expect improvement in most cases within 24 hours.
- **Ear Aches:** Most ear infections are caused by *Streptococcus pneumonia* or *H influenzae* bacteria. The new silver solution has been proven to kill both organisms. Lie down on bed or couch with affected ear facing up. Place five to seven drops of 10 ppm colloidal silver in ear. Remain in this lying position for a minimum of ten minutes, preferably for at least 30 minutes. Repeat two or three times per day. Noticeable improvement has been reported in as little as 4-24 hours.
- **Eye Infections:** The US EPA has reported that silver is neither an eye nor skin irritant. Silver has also been used in the eyes of newborn babies for over a hundred years because of its ability to combat eye infections. Spray or drip a few drops of the 10 ppm silver solution into the eye, two to three times a day to combat infection. Good results have been reported within 1-3 days. The new silver solution has also been used to alleviate sore or tired eyes, use the same as directed above.
- **Flu:** Take one tablespoon of 10 ppm silver solution by mouth two to three times per day. Hold the solution in the mouth (gargle, if possible) for three to five minutes before swallowing. Provided one takes the colloidal silver at the onset of the flu, noticeable improvement has been reported in one to three days. If the flu has become entrenched in the body, improvement is slower.

- **Food Poisoning:** The new silver solution has been proven to kill six types of bacteria that commonly cause food poisoning. Drink one ounce of 10 ppm solution at onset. Positive results have been reported in as little as 10 minutes, and as long as three hours.
- **Fungus Infections of the Feet:** Treat humans with mycotic toenails with the new silver solution. File the shine off the toenail (to increase porosity) and then spray the solution directly on the infected toenail or apply the solution directly with a cotton ball. Repeat two or three times daily.
- **Inflammation of the Joints:** Laboratory personnel have noted that in addition to its ability to kill bacteria and inhibit the growth of yeasts, the new silver solution is a powerful anti-inflammatory agent. Researchers have suggested that this may be one of the reasons that the pain from conditions like earaches and canker sores recedes so quickly. In order to informally test this theory, one researcher donated a bottle of the new silver solution to a young woman suffering from fibromyalgia, which causes a painful swelling in the joints and also the muscle tissue. She reported that after using one teaspoon per day of the 10ppm solution for one week, she was able to reduce her joint pain medication by 90%. She claimed that almost all the swelling was gone from the joints and also that her energy level had dramatically improved.
- **Insect Bites:** Excellent results have been reported using the new silver solution to alleviate the burning and itching of insect bites and stings. Relief from a multitude of different bugs bites have been reported including, mosquitoes, spiders, hornets and even blue centipedes from Hawaii. Spray the affected area or pour on a gauze or

cotton pad and hold the saturated pad on the affected area for 10-15 minutes, three times a day. Good results have been reported in as little as 30 minutes.

- **Laryngitis:** Spray on rear of throat and gargle with at least 1 tablespoon three to four times per day. Expect relief in two to three days. If the laryngitis is accompanied by a sore throat, see the section on "sore throat" below.
- **Mastitis:** Nursing mothers may be hesitant to take antibiotics while nursing their babies. It has been reported that one teaspoon four times a day has cleared up mastitis in two days.
- **Sinus Infection:** Irrigate with one-half to a whole teaspoon per nostril, three times per day. Relief can be noticeable in 24 hours, with complete remission often occurring in two to three days.
- **Sore Throat:** Both the antibacterial and the anti-inflammatory properties of silver solution may play a role in its affect on sore throats. Take one to two tablespoons, gargle for four to five minutes, and swallow. Repeat two or three times per day. It may also be helpful to spray or drip some solution into the nasal passages. Reports indicate noticeable improvement within 12-48 hours.
- **Sunburn:** Silver is the number one treatment for burns across the U.S. The solution successfully treats radiation burns. Success has also been reported using the product for sunburn. Spray the affected area with the 10 ppm silver solution, leave the solution wet on the skin until it dries. Repeat 2-3 times in the first 5-6 hours after occurrence. Relief has been reported in as little as 4-12 hours.
- **Thrush:** Place several drops in each side of the mouth four times a day. We have reports of this condition in a young child clearing up in two days.

- **Tooth Decay:** In laboratory tests the new silver solution has been proven to kill two of the primary bacteria implicated in tooth decay. Take one or two teaspoons, circulate the solution in your mouth for four to five minutes. Then swallow.
- **Urinary Tract Infection:** A woman who had a recurrent urinary tract infection for five years, reported that antibiotics would appear to kill the infection, but that it would reappear soon after she stopped taking the antibiotic. She took two teaspoons a day of the new silver solution for ten days and her doctor told her that the infection had cleared up completely. In laboratory tests it has been shown that the new silver solution has been able to kill seven different types of bacteria that cause urinary tract infections.
- **Vaginal Yeast Infection:** Take 1 teaspoon by mouth three times per day and use four to six teaspoons of the new silver solution in a six-ounce douche twice a day. Users have reported that infections have cleared up in as little as two days.
- **Water Purification:** Independent tests recently completed at a water purification laboratory indicate that in 1.5 minutes the new silver solution at a level of only 0.10 ppm killed 100% of the natural bacteria occurring in raw river water plus added bacteria. One eight-ounce bottle of 10 ppm could treat 800 ounces of water, or 6 ¼ gallons. It works best with non-chlorinated water.
- **General Well-Being:** Take one teaspoon of 10ppm silver solution once or twice daily as a mineral supplement. Research done earlier this decade, although inconclusive, suggests that this strengthens the immune system. At the very least, colloidal silver would appear to be a powerful prophylactic, killing harmful pathogens before they can become a threat to one's health. Confirming this, many people have reported that

taking the new silver solution on a daily basis has dramatically reduced the number of days they are sick.

The booklet by Kenneth S. Friedman, titled The New Silver Solution, discusses some of these uses for colloidal silver and is incorporated herein by reference in its entirety. For other uses of the solution in humans, and their effective concentrations, see Tables 1 and 2 in Appendix A.

In one aspect of the invention, the colloidal silver can be used for additional uses and in different concentrations. Generally, the concentration of the colloidal silver solution in this aspect of the invention ranges from about 0.05 to about 50 ppm. In other aspects of the invention, the solution is administered to humans in concentrations of about 2.5 ppm or less to kill bacteria, 10 to 14 ppm to kill viruses, 22 ppm to kill yeast and fungus, and 32 ppm for other uses. In humans, the silver colloid solution can be administered both topically and orally, without serious harm or risk to the patient. In one aspect, the solution is administered as a mineral supplement or as a therapeutic agent. It can be also be used as an alternative to antibiotics.

In another aspect of the invention, hydrogen peroxide (H_2O_2) can be added to the solution to give added benefits in killing bacteria, yeast and fungus. The concentration of the hydrogen peroxide generally can range from about 0.1% to about 3%. Hydrogen peroxide in the solution provides the benefit and synergism of breaking down cell walls, thereby allowing the anti-bacterial function of silver to act quicker than normal. A description of hydrogen peroxide is found in Exhibit 1, the disclosure of which is incorporated herein by reference.

The colloidal silver solution can be formed using any method known in the art. In one aspect of the invention, the solution is formed by the electrical process described in U.S. 6,214,299, the disclosure of which is incorporated by reference herein.

In one aspect of the invention, the colloidal silver solution was tested as an antibiotic alternative in Ghana, West Africa. The test has met with such surprising results that the Food and Drug Board of Ghana has approved the colloidal silver solution for drug registration. Testing of the product in hospitals by professional MD's, the colloidal silver solution was used as a treatment for a variety of diseases and conditions such as Malaria, Fungal Skin Infections, Vaginal Infections, Urinary Tract Infections, Tonsillitis, Pharyngitis, Gonorrhea, Conjunctivitis, Upper Respiratory Tract Infections, Nasal and Sinus problems, etc. In 58 human trials, the doctors reported no failures at all. In fact, almost all conditions showed full recovery within just 1-7 days, and in the case of one eye infection, the doctor reported almost immediate relief. The colloidal silver solution was used both internally and externally in these tests, and was administered in a solution having a 10 ppm concentration. A summary and data of these test results is located in Exhibit 2, the disclosure of which is incorporated herein.

In another aspect of the invention, the colloidal silver solution was used to treat malaria. Malaria is reportedly the number two infectious killer in the world, killing approximately 1.5 million people, mostly children, annually. Thousands of doctors and companies have been searching for a treatment for Malaria without success.

Of the first 58 patients treated in the hospitals with the colloidal silver solution, there were 11 reported Malaria patients. Some of the cases were reported as having "Severe Malaria." The patients' ages ranged 8 to 75 years old. All eleven cases were reported by the doctors as being fully recovered within seven days after used of the colloidal silver solution of the invention. Patients showed signs of recovery in an average of just under 3 days and were reported as fully recovered in an average of 5 days. In one aspect of the invention, these treatments consisted of administering the solution orally in a 10 ppm concentration three times

daily. The results and data from these tests are reported in Exhibit 2, the disclosure of which is incorporated herein by reference.

In another aspect of the invention, the colloidal silver solution was used to treat the MRSA (Methicillin-resistant *Staphylococcus aureus*) bacteria as well as *Candida albicans* yeast and the *Trichomonas vaginalis* protozoa. *Staphylococcus aureus* can cause serious blood poisoning when it enters a wound. It was once easily treated with penicillin, but it has now mutated to the point where it is totally resistant to it. The next defense on the antibiotic ladder has been Methicillin, but the strains of the bug that are resistant to Methicillin have become increasingly common, especially in hospitals. They are known as MRSA (Methicillin-resistant *Staphylococcus aureus*) – dubbed the superbug. People who contract the MRSA superbug infections in hospitals can die in a matter of days.

In the invention, 10 ppm colloidal silver solution was tested against six million colony forming units of the MRSA (per mL). The colloidal silver solution was able to kill 91.6% of the deadly bacteria in just 10 minutes, 98.8% in 30 minutes and 99.5% in an hour. Just 10 of these deadly bacteria per milliliter in your bloodstream could kill an adult human. The colloidal silver solution has been proven effective in killing hundreds of thousands of times that level of bacteria. The results and data from the tests on MRSA are found in Exhibit 3, the disclosure of which is incorporated herein by reference.

The invention was also tested against *Candida albicans* yeast (ATCC 10231) and the *Trichomonas vaginalis* protozoa (ATCC 30235). Both of these organisms are very problematic and can cause numerous difficulties including vaginal infections, diaper rash, thrush etc. Using in vitro testing, the colloidal silver solution was able to get close to a 100% kill on both organisms in just 10 minutes. These results of these tests open the potential for both using the colloidal

silver solution in a feminine hygiene product and as a treatment for diaper rash. These test results are also described in Exhibit 3, the disclosure of which is incorporated herein by reference.

In another aspect of the invention, colloidal silver solution can be used against Tuberculosis, which is the number one killing infectious disease world wide. It is important to note that just 10-15 bacterium per milliliter in the bloodstream could kill an adult human. In recent tests, the colloidal silver solution achieved a greater than 97% kill rate in just 45 minutes at just the 10 ppm level using in vitro testing. In these tests, the colloidal silver solution was tested against a challenge of approximately 47,000,000 bacterium per milliliter and achieved a kill rate of about 97.2% and about 97.3% in 45 minutes on the two tests. A summary of the test procedures and results is given in Exhibit 4, the disclosure of which is incorporated herein by reference.

Thus, colloidal silver solution can kill tuberculosis (TB), a disease that kills approximately three million people a year world wide. Because the colloidal silver solution has been proven non-toxic even under extreme usage, and because the TB bacterium attacks the lungs directly, one method of using the colloidal silver solution can be a direct application of the product to the lungs, such as by use of a nebulizer.

Based on the above testing, the products of the invention were officially listed in the Senate Registry as products for homeland defense. The registry lists the colloidal silver solution of the invention as a product that is "proven to kill bacteria such as Staph, [Tuberculosis], E-coli, Salmonella, a number of yeasts and even the Anthrax spore." See Exhibit 5, the disclosure of which is incorporated herein by reference.

What is claimed is:

1. A composition of matter, comprising a colloidal silver solution, ranging from 0.05 to 50 ppm of silver in water.
2. A method of treating ailments, comprising administering colloidal silver solution to the patient.
3. The method of claim 2, wherein the ailment is caused by bacteria.
4. The method of claim 2, wherein the ailment is caused by a virus.
5. The method of claim 2, wherein the ailments is caused by a fungus.
6. The method of claim 2, wherein the ailment is inflammation.
7. The method of claim 2, wherein the colloidal silver solution has a concentration of 0.05 to 50 ppm of silver in water.
8. The method of claim 2, wherein the ailment is malaria, fungal skin infections, vaginal infections, urinary tract infections, tonsillitis, pharyngitis, gonorrhea, conjunctivitis, upper respiratory tract infections, or nasal and sinus problems.
9. The method of claim 2, wherein the concentration of silver is about 10 ppm of silver or less.

APPENDIX A

Table 1: Ailments and pathogens that can be cured or killed by colloidal silver

Ailment	Pathogens	Silver Solution Effectiveness
Boils	Staphylococcus aureus	Killed @ 5 ppm
Bone Inflammation (Osteomyelitis)	Staphylococcus aureus	Killed @ 5 ppm
Bowel Infection (Bacillary Dysentery)	Shigella boydii	Killed @ 2.5 ppm
Burn Infections	Pseudomonas aeruginosa	Killed @ 5 ppm
Dental Plaque	Streptococcus mutans	Killed @ 5 ppm
Diarrhea (Bloody)	Shigella boydii	Killed @ 2.5 ppm
Diarrhea	E. Coli	Killed @ 2.5 ppm
Ear Infection	Haemophilus influenzae	Killed @ 1.25 ppm
Ear Infection	Streptococcus pneumoniae	Killed @ 2.5 ppm
Enteric Fever	Salmonella typhimurium	Killed @ 2.5 ppm
Epiglottitis (In children)	Haemophilus influenzae	Killed @ 1.25 ppm
Eye Infections	Staphylococcus aureus	Killed @ 5 ppm
Eye Infections (Corneal Ulcers-Keratitis)	Pseudomonas aeruginosa	Killed @ 5 ppm
Food Poisoning	Salmonella Arizona	Killed @ 5 ppm
Food Poisoning	Salmonella typhimurium	Killed @ 2.5 ppm
Food Poisoning	E. Coli	Killed @ 2.5 ppm
Heart Valve Infection (Endocarditis)	Streptococcus faecalis	Killed @ 2.5 ppm
Heart Valve Infection (Endocarditis)	Streptococcus gordonii	Killed @ 5 ppm
Meningitis	Haemophilus influenzae	Killed @ 1.25 ppm
Meningitis	Enterobacter aerogenes	Killed @ 2.5 ppm
Meningitis	Pseudomonas aeruginosa	Killed @ 5 ppm
Meningitis	Streptococcus pneumoniae	Killed @ 2.5 ppm
Nosocomial Infections (From hospitals)	Klebsiella pneumoniae	Killed @ 2.5 ppm
Nosocomial Infections (From hospitals)	Pseudomonas aeruginosa	Killed @ 5 ppm
Nosocomial Infections (From hospitals)	Streptococcus pyogenes	Killed @ 1.25 ppm
Pneumonia	Staphylococcus aureus	Killed @ 5 ppm
Pneumonia	Haemophilus influenzae	Killed @ 1.25 ppm
Pneumonia	Pseudomonas aeruginosa	Killed @ 5 ppm
Pneumonia	Streptococcus pneumoniae	Killed @ 2.5 ppm
Respiratory Tract Infections (Upper)	Streptococcus pyogenes	Killed @ 1.25 ppm

Respiratory Tract Infections	E. Coli	Killed @ 2.5 ppm
Respiratory Tract Infections (Lower)	Klebsiella pneumoniae	Killed @ 2.5 ppm
Scarlet Fever	Streptococcus pyogenes	Killed @ 1.25 ppm
Septicemia	Enterobacter aerogenes	Killed @ 2.5 ppm
Sinus Infections	Haemophilus influenzae	Killed @ 1.25 ppm
Sinusitis	Streptococcus pneumonie	Killed @ 2.5 ppm
Skin Infection (Impetigo)	Staphylococcus aureus	Killed @ 1.25 ppm
Skin Infections	Staphylococcus aureus	Killed @ 5 ppm
Skin Infections	Streptococcus pyogenes	Killed @ 1.25 ppm
Strep Throat	Streptococcus pyogenes	Killed @ 1.25 ppm
Suppurative Arthritis (In children)	Haemophilus influenzae	Killed @ 1.25 ppm
Throat Infections	Haemophilus influenzae	Killed @ 1.25 ppm
Tooth Decay	Streptococcus mutans	Killed @ 5 ppm
Urethritis (Men)	Trichomoniasis vaginalis	Killed @ 10 ppm
Urinary Tract Infections	E. Coli	Killed @ 2.5 ppm
Urinary Tract Infections	Klebsiella pneumoniae	Killed @ 2.5 ppm
Urinary Tract Infections	Pseudomonas aeruginosa	Killed @ 5 ppm
Urinary Tract Infections	Streptococcus faecalis	Killed @ 2.5 ppm
Urinary Tract Infections	Enterobacter aerogenes	Killed @ 2.5 ppm
Vaginitis (Women)	Trichomoniasis vaginalis	Killed @ 10 ppm
Wound Infections	E. Coli	Killed @ 2.5 ppm
Wound Infections	Enterobacter aerogenes	Killed @ 2.5 ppm
Wound Infections	Klebsiella pneumoniae	Killed @ 2.5 ppm
Wound Infections	Pseudomonas aeruginosa	Killed @ 5 ppm
Wound Infections	Streptococcus faecalis	Killed @ 2.5 ppm
Yeast Infections	Candida albicans	Killed @ 10 ppm

Table 2: Ailments and pathogens that can be inhibited, killed or cured by colloidal silver.

Bacterium	Causes	Inhibited at	Killed at
<i>Staphylococcus aureus</i>	Pneumonia	2.5 ppm	5 ppm
	Eye Infections		
	Skin Infections (boils, impetigo, cellulites, post-operative infections)		
	Toxic Shock Syndrome		
	Meningitis		
	Food Poisoning		
	Osteomyelitis		
<i>Shigella boydii</i>	Violent food poisoning	1.25 ppm	2.5 ppm
<i>Salmonella Arizona</i>	Food poisoning	2.5 ppm	5 ppm
<i>Salmonella typhimurium</i>	Food poisoning	2.5 ppm	2.5 ppm
	Enteric fever		
<i>Escheria coli 0157-H7</i> (Jack in the Box E. coli)	Food Poisoning	2.5 ppm	5 ppm
	Urinary Tract Infections		
	Respiratory Tract Infections		
	Diarrhea		
	Wound Infections		
<i>Escheria coli</i> (E. coli)	Food Poisoning	2.5 ppm	2.5 ppm
	Urinary Tract Infections		
	Respiratory Tract Infections		
	Diarrhea		
	Wound Infections		
<i>Haemophiles influenzae</i>	Otitis Media (ear infections)	1.25 ppm	1.25 ppm
	Pneumonia		
	Meningitis		
	Throat Infections		
	Sinus Infections		
	Epiglottitis in Children		
	Sinusitis		
	Suppurative Arthritis in Children		
<i>Klebsiella pneumoniae</i>	Lower Respiratory Tract Infections	2.5 ppm	2.5 ppm
	Pneumonia		
	Meningitis		
	Urinary Tract Infections		
	Wound Infections		
	Nosocomial Infections		

<i>Klebsiella oxytoca</i>	Same as above	2.5 ppm	2.5 ppm 0.1 ppm in water
<i>Enterobacter aerogenes</i>	Wound infections	2.5 ppm	2.5 ppm
	Bacteremia		
	Urinary Tract Infections		
	Meningitis		
<i>Pseudomonas aeruginosa</i>	Severe Burn Infections	2.5 ppm	5 ppm
	Wound Infections		
	Keratitis		
	Meningitis		
	Pneumonia		
	Urinary Tract Infections		
	Nosocomial Infections		
<i>Streptococcus pneumoniae</i>	Pneumonia	2.5 ppm	5 ppm
	Meningitis		
	Sinusitis		
	Otitis Media		
<i>Streptococcus pyogenes</i>	Strep Throat	1.25 ppm	1.25 ppm
	Scarlet Fever		
	Impetigo		
<i>Streptococcus faecalis</i>	Urinary Tract Infections	5 ppm	5 ppm
	Endocarditis		
	Wound Infections		
<i>Streptococcus mutans</i>	Dental Plaque	5 ppm	5 ppm
	Tooth Decay		
<i>Streptococcus gordonii</i>	Tooth Decay	5 ppm	5 ppm
	Infective Endocarditis		

60475657.060303

Attorney Docket No. 40056-0002

EXHIBIT 1

6/3/2003

Hydrogen Chloride

160475657 : 060303 508

moist air. Condensible to a liquid at low temps. d. 2.71 (air = 1).

Hydrogen Chloride. HCl; mol. wt. 36.47; Cl 97.23%. Is made by heating NaCl with H_2SO_4 or from Cl and hydrogen. It is a colorless, pungent, corrosive gas, fuming in air. d. 1.26 (air = 1). Liquefies at -102° . Very soluble in water, alcohol; also in ether.

Hydrogen Cyanide. HCN; mol. wt. 27.03. C 44.43%, H 3.72%, N 51.82%, CN 98.26%.

Colorless gas or liquid; characteristic odor; very weakly acid (does not reddens litmus); burns in air with a blue flame; *intensely poisonous* even when mixed with air. d. gas 0.941 (air = 1); d. liquid 0.687. m. -14° . b. 26° . Miscible with water, alcohol; slightly soluble in ether.

Use: The compressed gas is used for exterminating rodents and insects in ships and for killing insects on trees, etc. *Must be handled only by specially trained experts. Commercially available.*

Toxicity: High concn. produces increased respiration (causing increased intake of cyanide); then labored respiration, paralysis, loss of consciousness, convulsions and respiratory arrest. Throat constriction, headache, vertigo, nausea and vomiting may occur. Chronic exposure over long periods reported to be associated with fatigue, weakness, dermatitis, enlargement of the thyroid, G.I. disturbances, speech difficulty, confusion, delirium and death. Exposure to 160 p.p.m. for $\frac{1}{2}$ to 1 hr. may endanger life. Max. allowable concn. 10 p.p.m. Death may result from a few min. exposure to 300 p.p.m. Average fatal dose: 50 to 60 mg.

Hydrogen Dioxide *see* Hydrogen Peroxide.

Hydrogen Dioxide Solution *see* Hydrogen Peroxide Solution, 3%.

Hydrogen Ferrocyanide *see* Hydroferrocyanic Acid.

Hydrogen Fluoride. HF; mol. wt. 20.01; fluorine, 94.96%. Is a colorless gas, highly irritating, corrosive, and poisonous. d. 0.921 (air = 1). d. 0.987 (liq.). m. -92.3° . b. 19.4° . Very soluble in water, alcohol, slightly in ether.

Hydrogen Iodide. HI; mol. wt. 127.93; I 99.21%. Is prepared from iodine and H_2S , or from iodine and hydrogen in the presence of palladium or chromic acid. It is a colorless, very acrid gas, readily condensible to a liquid. d. 5.66 (air = 1). b. -35° . Solidif. -55° . Very soluble in water with evolution of much heat.

Med. Use: Has been used in 10% soln. in iodide therapy and as an expectorant.

Hydrogen Oxide *see* Water.

Hydrogen Peroxide. Hydrogen dioxide. Discovered by Thénard in 1818. Made from

Marketed as a soln. in water in concentrations from 3 to 30% by weight.

Solutions of hydrogen peroxide gradually deteriorate and are usually stabilized by the addition of acetanilide or similar organic materials. Agitation or contact with rough surfaces, metals, or many other substances accelerates decomposition. Rapidly decomposed by alkalis, finely divided metals; the presence of mineral acid renders it more stable.

Anhydr. hydrogen peroxide (H_2O_2 ; mol. wt. 34.02; available oxygen 47.03%) is a colorless, rather unstable liquid; bitter taste; caustic to the skin. Distillable in high vacuum. May decompose violently if traces of impurities are present. d. 1.463. m. -1.7° . b. 152° . Miscible with water; soluble in ether; insoluble in petrol. ether; decomposed by many organic solvents.

Hydrogen Peroxide Solution 3%. Hydrogen dioxide solution. Contains 2.5-3.5% by wt. of H_2O_2 = 8-12 vols. oxygen.

Colorless, slightly acid liquid. d. about 1.00. Foams in the mouth. *Keep protected from light and in a cool place. Incompat.: Alkalis, ammonia and their carbonates, albumin, balsam Peru, phenol, charcoal, chlorides, alkali citrates; ferrous, mercurous or gold salts; hypophosphites, iodides, lime water, permanganates, sulfites, tinctures, and organic matter in general.*

Use: White discharge printing on indigo-dyed wool; bleaching feathers, hair, silk, straw, ivory, flour, bone, gelatin, and textile fabrics; renovating old paintings, engravings; as oxidizer in manuf. dyes; disinfecting water and hides; artificially aging wines, liquors, etc.; refining oils and fats; as antichlor; with paraphenylenediamine as a dye for furs, dead hair, etc.; in photography as hypo eliminant; with NaOH for cleaning metal surfaces, for gilding, silvering, etc. In pharmaceutical preps, mouthwashes, dentifrices, sanitary lotions. *Grades available: U.S.P., technical.*

Med. Use: Antiseptic. **Caution:** Continued use in the mouth can cause hypertrophied papillae of the tongue.

Vet. Use: As Med. Use.

Hydrogen Peroxide Solution 30%. Contains 30% by wt. of H_2O_2 = 100 vols. of oxygen.

Clear, colorless liquid. d. about 1.11. Miscible with water. This peroxide soln. now is replacing the 3% soln. for industrial uses being diluted to the required strength immediately before use. It also is used for making the 3% soln.

Caution: Strong Oxidant. Avoid contact with skin and eyes—wear rubber gloves and goggles. Avoid contact with combustible materials. Drying of concentrated product on clothing or other combustible materials may cause fire. In case of contact, immediately flush with plenty of water for at least 15 min.

hydrochloric acid

the sutures, bulging scalp veins. The face and the eyes seen: behavior includes vomiting, leg spastic reflex actions. Lower brain-stem skull becomes destroyed, and the sutures, and heart surviving the neck after the crania.

skull has formed, symptoms are primarily neurological and include headache, swelling of the optic disc, and loss of muscular coordination. Hydrocephalus in infants is suspected when head growth is above the normal rate. In all age groups diagnosis is confirmed by such procedures as spinal fluid examination, air encephalography, arteriography, and echoccephalography.

***TREATMENT:** Treatment is usually surgery to correct the ventricular blockage, reduce the making of spinal fluid, or shunt the excess fluid to the heart or peritoneal cavity. Surgically treated hydrocephalus with continued neurosurgical and medical management has a survival rate of approximately 80%, but prognosis depends largely on the cause of the condition. Hydrocephalus is often found with myelomeningocele, in which case there is a less favorable prognosis.

***PATIENT CONSIDERATIONS:** Primary care of the child with hydrocephalus consists of good nutrition and proper positioning and support to prevent extra strain on the neck. Parents need to know the signs of shunt malfunction or infection and how to pump the shunt.

hydrochloric acid, a compound of hydrogen and chlorine. Hydrochloric acid is secreted in the stomach. It is a main part of gastric juice.

hydrochlorothiazide, a diuretic used to treat hypertension and swelling (edema).

***CAUTION:** Anuria or allergy to this drug, to other thiazide medication, or to sulfonamide derivatives prevents its use.

***ADVERSE EFFECTS:** Among the more serious side effects are low or high blood sugar, high uric acid, and allergic reactions.

hydrocholeretics, drugs that stimulate the making of bile with a few specific gravity or with a minimal proportion of solid constituents.

Hydrocil, a trademark for a laxative (psyllium hydrophilic muciloid).

hydrocodone bitartrate, a narcotic given to treat cough.

***CAUTION:** Drug dependence or allergy to this drug prevents its use.

***ADVERSE EFFECTS:** Among the more serious side effects are drug dependence and respira-

hydronephrosis

ic acetate, hydrocortisone, hydrocortisone cortisone.

eroid, used topically.

gent, ingal skin diseases.

ion is slowed or altered its use. Among the more serious systemic effects of great use. Local occur.

hydrocortisone, a glucocorticoid (hydrocortisone acetate).

HydroDIURIL, a trademark for a diuretic (hydrochlorothiazide).

hydroflumethiazide, a diuretic used to treat hypertension and swelling.

***CAUTION:** Anuria or allergy to this drug, to other thiazide medication, or to sulfonamide derivatives prevents its use.

***ADVERSE EFFECTS:** Among the more serious side effects are blood disorders, low blood pressure, high blood calcium, high blood sugar, high uric acid, and allergic reactions.

hydrogen (H₂), a gaseous element, normally a colorless, odorless, highly inflammable gas. As part of water, hydrogen is crucial in the interaction of acids, bases, and salts in the body and in the fluid balance needed for the body to survive. Hydrogen enables water to dissolve the different substances on which the body depends, as oxygen and food substances.

hydrogenation. See reduction.

hydrogen peroxide, a topical anti-infective. It is used to cleanse open wounds, as a mouthwash, and to aid in removing earwax.

***CAUTION:** Irritations to skin or mucous membranes or allergy to this agent prevent its use.

***ADVERSE EFFECTS:** There are no known side effects.

hydromorphone hydrochloride, a narcotic used to treat moderate to severe pain.

***CAUTION:** It is used with caution in many cases, including head injuries, asthma, impaired kidney or liver function, or unstable heart. Allergy to this drug prevents its use.

***ADVERSE EFFECTS:** Among the most serious side effects are drowsiness, dizziness, nausea, constipation, slowed breathing and blood flow, and drug addiction.

hydronephrosis /hi'drōnefrō'sis/, swelling of the pelvis by urine that cannot flow past a blockage in a ureter. Ureteral obstruction may be caused by a tumor, a stone lodged in the ureter, inflammation of the prostate gland, or a urinary-tract infection. The person may have pain in the flank. Surgery to remove the blockage may be needed. Prolonged hydro-

ually stabilized by the addition of acetanilide or similar organic materials. Agitation or contact with rough surfaces, metals or many other substances accelerates decomposition. Rapidly dec by alkalies, finely divided metals; the presence of mineral acid renders it more stable.

Caution: Potential symptoms of overexposure are irritation of eyes, nose and throat; corneal ulceration; erythema, scales on skin; bleaching of hair. See *NIOSH Pocket Guide to Chemical Hazards* (DHHS/NIOSH 90-117, 1990) p 126.

USE: A 90% soln is used in rocket propulsion. As dough conditioner, maturing and bleaching agent in food.

THERAP CAT: Antiseptic; disinfectant.

THERAP CAT (VET): Topical antiseptic and cleansing agent in a dilute soln.

4840. Hydrogen Peroxide Solution 3%. Hydrogen peroxide soln; oxydol. Contains 2.5-3.5% by wt of H_2O_2 = 112 vols oxygen.

Colorless, slightly acid liq. $d \sim 1.00$. Foams in the south. *Keep protected from light and in a cool place. Incompat:* Alkalies, ammonia and their carbonates, albumin, xasam Peru, phenol, charcoal, chlorides, alkali citrates; chromous, mercurous or gold salts; hypophosphites, iodides, lime water, permanganates, sulfites, tinctures, and organic matter in general.

USE: In the plastics industry; white discharge printing on odigo-dyed wool; bleaching feathers, hair, silk, straw, wool, flour, bone, gelatin, and textile fabrics; removing old paintings, engravings; as oxidizer in manuf dyes; disinfecting water and hides; artificially aging wines, liquors, etc.; disinfecting oils and fats; as antichlor; with paraphenylenediamine as a dye for furs, dead hair, etc.; in photography as hypo eliminant; with H_2O_2 for cleaning metal surfaces, for plating, silvering, etc. In pharmaceutical preps, mouthwashes, dentifrices, sanitary lotions.

THERAP CAT: Anti-infective (topical).

THERAP CAT (VET): Topical antiseptic and cleansing agent.

4841. Hydrogen Peroxide Solution 30%. Superoxol. Contains 30% by wt of H_2O_2 = 100 vols of oxygen.

Clear, colorless liquid. *Strong oxidizing agent!* $d \sim 1.11$. Miscible with water. Now replacing the 3% soln for industrial uses; diluted to the required strength immediately before use. It also is used for making the 3% soln.

Caution: Avoid contact with skin and eyes—wear rubber gloves and goggles. Avoid contact with combustible materials. Drying of concd product on clothing or other combustible materials may cause fire. In case of contact, immediately flush with plenty of water for at least 15 min; for eyes, get medical attention. Avoid contamination from any source, including metals, dust, etc. Such contamination may cause rapid decompn, generation of large quantities of oxygen gas and high pressures.

Store in original closed container. Be sure that the container vent is working satisfactorily. Do not add any other product to container. When empty, rinse thoroughly with lean water.

4842. Hydrogen Selenide. Selenium hydride. H_2Se ; mol wt 80.98. H 2.49%, Se 97.51%. Prep'd by heating selenium and hydrogen in a sealed tube at 440° : Hauteville, *Bull. Soc. Chim.* [2] 7, 198 (1867); by passing a mixture of hydrogen and selenium vapor over pumice stone at 440° : Cornwinder, *Ann. Chim. Phys.* [3] 34, 77 (1852); by warming potassium or ferrous selenide with hydrochloric acid: Berzelius, *Acad. Handl. Stockholm* 39, 13 (1818); by the action of water on aluminum selenide: Fonzen-Diacon, *Traité de Chimie Minérale, Paris* 1, 469 (1904); Waitkins, *Inorg. Syn.* 2, 183 (1946).

Gas. Disagreeable odor. $d_{420}^{25} 2.12$. bp -41.3° . Liquefies at 0° under a pressure of 6.6 atm; at 18° , 8.6 atm; at 32° , 11.5 atm; at 100° , 47.1 atm; at the crit temp 137° , 91.0 atm. mp -65.73° . v.p. at -30° , 1.75 atm; v.p. at 0.2° , 4.5 atm; p. at 30.8° , 12 atm. K_1 at $25^\circ = 1.30 \times 10^{-4}$; K_2 at $25^\circ = 1.0 \times 10^{-11}$. Solly in water (ml/100 ml): 377 (4°); 270 (22.5°). Sol in carbonyl chloride and carbon disulfide. Unites directly with most metals to form metal selenides. Approx LD_{50} (30 min) in guinea pigs: 6 ppm. *Handbook of Toxicology* vol. 1, W. S. Spector, Ed. (Saunders, Philadelphia, 1956) pp 340-341.

Caution: Potential symptoms of overexposure are irritation of eyes, nose and throat; nausea, vomiting and diarrhea; metallic taste, garlic breath; dizziness, lassitude and fatigue. See *NIOSH Pocket Guide to Chemical Hazards* (DHHS/NIOSH 90-117, 1990) p 128.

4843. Hydrogen Sulfide. Sulfureted hydrogen; "hydro-sulfuric acid". H_2S ; mol wt 34.08. H 5.91%, S 94.09%. Evolved from numerous environmental natural sources such as bacterial decomposition of vegetable and animal proteinaceous material. Occurs naturally as a component of crude petroleum, natural gas, volcanic gas and sulfur springs. Also a pollutant released into the environment as a by-product of a variety of industrial operations. Lab prep'n: Bickford, Wilkinson, *Inorg. Syn.* 1, 111 (1939). Purification: Ward et al., *ibid.* 3, 14 (1950). Toxicity studies: E. H. Vernot et al., *Toxicol. Appl. Pharmacol.* 42, 417 (1977); M. F. Tansy et al., *J. Toxicol. Environ. Health* 8, 71-88 (1981). Review of toxicity and properties: R. O. Beauchamp, Jr., et al., *CRC Crit. Rev. Toxicol.* 13, 25-97 (1984); of toxicology: R. J. Reiffenstein et al., *Ann. Rev. Pharmacol. Toxicol.* 32, 109-134 (1992).

Flammable, poisonous gas with characteristic odor of rotten eggs, perceptible in air at concns of 0.02-0.13 ppm, sweetish taste. Burns in air with pale blue flame. Ignition temp 260° . Explosive limits when mixed with air: lower limit 4.3% by vol, upper limit 46% by vol. mp -85.49° ; bp -60.33° . Giauque, Blue, *J. Am. Chem. Soc.* 58, 831 (1936). Heavier than air; 1.5392 g/l (0° ; 760 mm). $d_{20}^{20} 1.19$ (air = 1.00). Vapor pressure 18.75×10^5 Pa. One gram H_2S dissolves in 187 ml water at 10° , in 242 ml water at 20° , in 314 ml water at 30° ; in 94.3 ml abs alcohol at 20° ; in 48.5 ml ether at 20° . Sol in glycerol, gasoline, kerosene, carbon disulfide, crude oil. Water solns $\sim H_2S$ are not stable, absorbed oxygen causes the formation of elemental sulfur, and the solns become turbid rapidly. In a 50:50 v/v mixture of glycerol and water the precipitation of sulfur is retarded considerably. pH of freshly prep'd sat'd water soln 4.5. pK_{a1} 7.04; pK_{a2} 11.96. LC_{50} in mice, rats (ppm): 634, 712 (1 hr inhalation) (Vernot). LC_{50} in rats (ppm): 444 (4 hr inhalation) (Tansy).

Caution: Highly toxic, can be fatal. Irritant and chemical asphyxiant. Insidious poison, since sense of smell may be fatigued and fail to give warning of high concns. Direct contact with gas may cause irritation of eyes and respiratory tract resulting in keratoconjunctivitis, photophobia, lacrimation, corneal opacity; rhinitis, laryngitis, cough, bronchopneumonia. Direct contact with solution may cause skin irritation, erythema. Potential symptoms of overexposure by inhalation include salivation, GI disturbances; giddiness, headache, vertigo, confusion, unconsciousness; tachypnea, tachycardia, sweating, fatigue. Exposure to very high vapor concentrations may result in systemic intoxication leading to paralysis of respiratory center of brain, apnea and sudden collapse. See *Clinical Toxicology of Commercial Products*, R. E. Gosselin et al., Eds. (Williams & Wilkins, Baltimore, 5th ed., 1984) Section III, pp 198-202; *NIOSH Pocket Guide to Chemical Hazards* (DHHS/NIOSH 94-116, 1994) p 170.

USE: To produce elemental sulfur and sulfuric acid; in manuf of heavy water and other chemicals; in metallurgy; as analytical reagent.

4844. Hydrogen Telluride. H_2Te ; mol wt 129.62. H 1.56%, Te 98.44%. Prep'd by the action of H_2O or HCl on aluminum telluride; by electrolysis of a 50% soln of sulfuric or phosphoric acid with a Te cathode: Dennis, Anderson, *J. Am. Chem. Soc.* 36, 882 (1914); Fehér in *Handbook of Preparative Inorganic Chemistry* vol. 1, G. Brauer, Ed. (Academic Press, New York, 2nd ed., 1963) pp 438-441.

Colorless gas. Offensive, garlic-like odor. *Highly poisonous!* mp -49° . bp -2° . $d_{20}^{20} 2.68$. Wt of one liter of the gas: 6.234 g. Liquid H_2Te is dec immediately by light. The dry gas is stable to light, but dec in the presence of dust, traces of moisture, rubber, cork, etc. Sol in water with fairly quick decompn. A sat'd aq soln is about 0.1N.

Caution: Imparts offensive odor to breath. Symptoms similar to hydrogen selenide, q.v.

4845. Hydrogen Tetracarbonylferrate(II). Iron hydrocarbonyl; iron tetracarbonyl dihydride. $C_4H_2FeO_4$; mol wt 169.90. C 28.28%, H 1.19%, Fe 32.87%, O 37.67%. H_2Fe-

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EXHIBIT 2

6/3/2003

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The Hospitals

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Fifty-eight patients at three hospitals in Ghana, West Africa were treated with ASAP Solution® by their attending physicians. The studies were performed at the Air force Station Hospital under the direction of Dr. Kwabiah, the Korle-Bu Teaching Hospital under the direction of Dr. Sackey, and the Justab Clinic/Maternity under the direction of Dr. Abraham.

Diversity Of Use

The ASAP Solution® was tested on a wide diversity of human ailments including malaria, upper respiratory tract infections, urinary tract infections, sinusitis, vaginal yeast infections, eye, nose and ear infections, cuts and fungal skin infections and sexually transmitted diseases, such as gonorrhea. The ASAP Solution® was used both internally and externally as an alternative to antibiotics.

The Product

All treatments were performed using the American Biotech Labs ASAP Solution® (ASAP) at a strength of 10 parts per million.

Summary Data

The data were summarized by **ailment treated**, **average dosage used** for treatment, **average time before signs of recovery were observed**, and **average time under treatment to obtain full recovery** (as deemed by the doctors).

Abdominal Pain & Diarrhea

Number of Patients:	1
Average Dosage:	10 ml. (two teaspoons) of ASAP three times in one day.
Signs of Recovery:	Not noted
Full Recovery:	1 day

Bronchitis

Number of Patients: 2
Average Dosage: 5 ml (one teaspoon) of ASAP twice daily.
Signs of Recovery: 1.5 days
Full recovery: 3.0 days.

Vaginal Yeast (Candida) Infection

Number of Patients: 5
Average Dosage: 10 ml (two teaspoons) of ASAP twice daily as a vaginal douche.
Signs of Recovery: 3 days.
Full recovery: 5.5 days

Conjunctivitis (Eye Infection)

Number of Patients: 2
Average Dosage: Several drops of ASAP solution in the infected eye, twice daily.
Signs of Recovery: Not noted
Full Recovery: 1 day.

External Cuts & Infection (Conditions included Staph skin infections, septic ulcers, and infected abscesses)

Number of Patients: 6 .
Average Dosage: 5 ml (one teaspoon) of ASAP twice daily.
Signs of Recovery: 2.2 days
Full Recovery 3.0 days.

External Otitis (Ear Infection)

Number of Patents: 6
Average Dosage: 2 drops of ASAP in the infected ear three times daily.
Signs of Recovery: 1.7 days
Full Recovery: 3.5 days.

Otitis Media (Middle Ear Infection)

Number of Patients: 1
Dosage: 2 drops of ASAP in the infected ear, three times daily.
Signs of Recovery: 2.0 days.
Full Recovery: 4.0 days.

Fungal Skin Infection

Number of Patents: 2
Average Dosage: 10 ml (two teaspoons) of ASAP three times daily.
Signs of Recovery: 4.5 days
Full Recovery: 8.0 days

Gonorrhea

Number of Patients: 2
Average Dosage: 10 ml (two teaspoons) of ASAP two times daily.
Signs of Recovery: 3.5 days and were reported
Full Recovery: 6.0 days.

Malaria

Number of patients: 11
Average Dosage: 10 ml (two teaspoons) of ASAP three times daily.
Signs of Recovery: 2.4 days
Full Recovery: 5.0 days.

Mouth Problems (Halitosis & Gingivitis)

Number of patients: 2
Average Dosage: Both patients were given ASAP as a mouth wash.
Signs of Recovery: Not reported
Full Recovery: 3 (gingivitis)
1 (halitosis)

Pelvic Inflammatory Disease

Number of Patents: 1
Average Dosage: 5 ml (one teaspoon) two times daily as a vaginal douche.
Signs of Recovery: 2 days
Full Recovery: 5 days.

Pharyngitis (Sore Throat)

Number of Patents: 4
Average Dosage: 10 ml (two teaspoons) of ASAP, three times daily as a gargle.
Signs of Recovery: 3.75 days
Full Recovery: 5.25 days.

Retro Viral Infection, HIV

Number of Patents: 1
Average Dosage: 5 ml (one teaspoon) of ASAP two times daily.
Signs of Recovery: 4 days
Full Recovery: 5 days

Sinusitis/ Rhinitis (Nasal Infections)

Number of Patients 6 (4 patients with sinusitis and 2 patients with rhinitis)
Average Dosage: 2 drops of ASAP in their nasal passages, three times daily.
Signs of Recovery: 1.6 days
Full Recovery 3.2 days.

Tonsillitis

Number of Patients: 1
Average Dosage: 10 ml three times daily as a gargle.
Signs of Recovery: 2 days
Full Recovery: 7 days.

Upper Respiratory Tract Infection

Number of Patients: 2
Average Dosage: 5 ml (one teaspoon) three times daily.
Signs of Recovery: 3 days
Full Recovery: 6 days.

Urinary Tract Infections

Number of Patients: 3
Average Dosage: 10 ml (two teaspoons) two to three times daily.
Signs of Recovery: 3.3 days
Full Recovery: 5.6 days.

Number of Patents: 1
Average Dosage: 5 ml (one teaspoon) of ASAP two times daily.
Signs of Recovery: 4 days
Full Recovery: 5 days

Sinusitis/ Rhinitis (Nasal Infections)

Number of Patients 6 (4 patients with sinusitis and 2 patients with rhinitis)
Average Dosage: 2 drops of ASAP in their nasal passages, three times daily.
Signs of Recovery: 1.6 days
Full Recovery 3.2 days.

Tonsillitis

Number of Patients: 1
Average Dosage: 10 ml three times daily as a gargle.
Signs of Recovery: 2 days
Full Recovery: 7 days.

Upper Respiratory Tract Infection

Number of Patients: 2
Average Dosage: 5 ml (one teaspoon) three times daily.
Signs of Recovery: 3 days
Full Recovery: 6 days.

Urinary Tract Infections

Number of Patients: 3
Average Dosage: 10 ml (two teaspoons) two to three times daily.
Signs of Recovery: 3.3 days
Full Recovery: 5.6 days.

Summary

The 58 patients who participated in these studies were treated for one or more of the 18 different ailments studied. In every case, the doctors were using the ASAP Solution® in 10ppm strength as an antibiotic alternative. The doctors reported that, in almost every case, their patients achieved full recovery in seven days or less. At this time, additional testing is under way.

REPORTS from GHANA Hospitals using ASAP SOLUTION	10 ppm		
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REPORTS from GHANA Hospitals using ASAP SOLUTION								10 ppm	
Medical Officer									Clinic/Hospital
Dr. E. Sackey									Korle-Bu Teaching Hospital
Patient ID	Age	Type of Disease	Date Admin.	Dosage	Cure Signs	Final Cure Date	General Observation & Remarks		
7 Obeng	33	External Otitis, Bilateral	6/13/2002	2 drops/ 3x daily	6/15/2002	6/17/2002	Nasal Congestion resolved		
8 Acquanda	30	Allergic Rhinitis	6/13/2002	2 drops/ 3x daily	6/14/2002	6/16/2002			
9 Dogbe	40	Right External Otitis	6/15/2002	2 drops/ 3x daily	6/15/2002	6/18/2002			
10 Asaule	39	Chronic Suppurative Otitis Media	6/17/2002	2 drops/ 3x daily	6/19/2002	6/21/2002	Used other ear drops w/ no improvement		
11 Grant	9	External Otitis, Left	6/24/2002	2 drops/ 3x daily	6/25/2002	6/26/2002			
12 Tenteh	37	Pharyngitis	6/27/2002	Gargling 3x daily	6/30/2002	7/1/2002	Reduced nasal congestion		
13 Kasah	31	Upper respiratory tract infection	6/27/2002	Nasal Application	7/1/2002	7/3/2002			
14 Olori	21	Pharyngitis	8/7/2002	Gargling 3x daily	8/15/2002	8/18/2002	Cleared very fast		
15 Isengndi	46	Nasal Congestion	7/8/2002	2 drops/ 3x daily	7/8/2002	7/10/2002			
16 Mensah	16	Allergic Rhinitis	7/8/2002	2 drops/ 3x daily	7/8/2002	7/12/2002	Gargling		
17 Larleh	9	Right External Otitis	7/10/2002	2 drops/ 3x daily	7/12/2002	7/13/2002			
18 Sackey		Pharyngitis	7/12/2002	10 ml 3x daily	7/13/2002	7/14/2002	No Improvement w/ H2O2. Cured w/ ASAP		
19 Yesod		Abdominal pain & diarrhea	7/15/2002	10 ml 3x daily	7/16/2002	7/16/2002			
20 Hyfud		Right Maxillary Sinusitis	7/20/2002	10 ml 3x daily	7/23/2002	7/25/2002			
21 Asiedu	55	External Otitis, Left	8/1/2002	2 drops/ 3x daily	8/4/2002	8/9/2002			
22 Hansen	46	Acute Pharyngitis	8/5/2002	Gargling 3x daily	8/8/2002	8/10/2002			
23 Marley	30	Itchy Ears	8/5/2002	2 drops/ 3x daily	8/6/2002	8/6/2002			

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REPORTS from GHANA Hospitals using ASAP SOLUTION						
Patient ID	Age	Type of Disease	Date Admin.	Dosage	Cure Signs	Final Cure Date
Mulba	27	Fungal Skin Infect, Eczema, Cloxacillin	3/22/2002	10 ml 3x daily	3/27/2002	3/30/2002
Aquash	27	Candida, Vaginal Infection	3/25/2002	10 ml 2x daily/Vag Dch		
Paye	31	Candida, Vaginal Infection	3/25/2002	10 ml 2x daily/Vag Dch	3/28/2002	3/30/2002
Issaka	18	Malaria, UTI	3/26/2002	10 ml 2x daily	3/29/2002	3/31/2002
Awud	35	Sever UTI, Malaria	3/26/2002	10 ml 3x daily	3/29/2002	4/2/2002
Tandoh	16	Candida, Vaginal Infection	2/5/2002	10 ml 2x daily/Vag Dch	2/5/2002	2/8/2002
Sape	20	Candida, Vaginal Infection	2/8/2001	10 ml 2x daily, Vag Dch	2/12/2002	2/14/2002
Dua-Baming	45	Fungal Skin Infection	2/8/2002	10 ml 2x daily	2/12/2002	2/18/2002
Adams	25	Lacunar Tonsillitis	2/10/2002	10 ml 3x daily, Gargle	2/12/2002	2/17/2002
Quarshie	75	Pharyngitis, Malaria	3/18/2002	10 ml 3x daily, Gargle	3/21/2002	3/25/2002
Danso	8	Chronic Malaria, trtd. w/ chloroquin	3/21/2002	7.5 ml 2x daily	3/25/2002	3/28/2002
Sarpong	40	Gonorrhea, took cyprofoxacin-7 days	3/21/2002	10 ml 2x daily	3/24/2002	3/26/2002
Sesay	53	Malaria, Pharyngitis	3/21/2002	10 ml 2x daily, Gargle	3/24/2002	3/26/2002

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Attorney Docket No. 40056-0002

EXHIBIT 3

USP Preservative Rapid Challenge Test Results

OrderID 118
CompanyName
Date Began 6/21/2002
Order Description ASAP 10ppm

Candida albicans ATCC10231**Trichomonas vaginalis ATCC 30235**

Initial Conc.	6.8e5 cfu's/mL	Initial Conc.	6.0e4 cfu's/mL
10 Min.	None Detected cfu's/mL	10 Min.	0 % Motility of 100 Organisms
30 Min.	None Detected cfu's/mL	30 Min.	0 % Motility of 100 Organisms
1 Hour	None Detected cfu's/mL	1 Hour	0 % Motility of 100 Organisms
1 Day	None Detected cfu's/mL	1 Day	0 % Motility of 100 Organisms

Notes: One hundred (100) *Trichomonas vaginalis* parasites were analyzed via microscopy for motility of flagella. Zero (0) of the one-hundred (100) parasites demonstrated motility at ten (10) minutes indicating inhibitory or lethal properties of the Silver solution on the parasites. The outer membranes of twenty-five (25) percent of the parasites had ruptured in one (1) day.

* Initial Concentration represents the total concentration of organisms per mL of solution.

** Sensitivity of bacterial, yeast, and mold tests is 1 log.


Quality Manager

60475657 .060303

USP Preservative Rapid Challenge Test Results

OrderID 136
Company Name
Date Began 9/7/2002
Order Description ASAP Silver Solution 10ppm

MRSA ATCC BAA-44


Initial Conc.	6.0e6 cfu's/mL	
10 Min.	500,000 cfu's/mL	91.6 % Kill
30 Min.	70,000 cfu's/mL	98.8 % Kill
1 Hour	30,000 cfu's/mL	99.5 % Kill
1 Day	< 10 cfu's/mL	

Notes:

Started With 6,000,000 CFU's/mL

* Initial Concentration represents the total concentration of organisms per mL of solution.

** Sensitivity of bacterial, yeast, and mold tests is 1 log.


Quality Manager

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Attorney Docket No. 40056-0002

EXHIBIT 4

FINAL REPORT

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TUBERCULOCIDAL KILL TIME STUDY:
ASAP COLLOIDAL SILVER PRODUCT (10 PPM)

PROTOCOL NO. 200108804-01

LABORATORY NO. 181806

PREPARED FOR:

60475657.060303

TUBERCULOCIDAL KILL TIME STUDY
ASAP COLLOIDAL SILVER PRODUCT (10 PPM)

LABORATORY NUMBER:	181806
PROTOCOL NUMBER:	200108804-01
SAMPLE SOURCE:	
SAMPLE IDENTIFICATION:	ASAP Solution (10 ppm) Lot #0845
DEVIATIONS:	None
DATA ARCHIVE LOCATION:	Sequentially by lab number
NUMBER OF TEST SAMPLES:	One 236 mL bottle
PROTOCOL APPROVAL DATE:	02 Apr 2001
SAMPLE RECEIVED DATE:	02 Apr 2001
LAB PHASE START DATE:	02 Apr 2001
LAB PHASE COMPLETION DATE:	16 May 2001
REPORT ISSUE DATE:	16 May 2001
TOTAL NUMBER OF PAGES:	13

REFERENCES:

United States Environmental Protection Agency. 1986. Office of Pesticides and Toxic Substances. Data Call-In Notice For Tuberculocidal Effectiveness Data For All Antimicrobial Pesticides With Tuberculocidal Claims. Received Jun 13, 1986.

INTRODUCTION:

This report describes the procedures for the evaluation of ASAP colloidal silver product (10 ppm) from for tuberculocidal efficacy. This report is based on the Tuberculocidal Activity Test Method as accepted by the EPA on 11 Dec 1985. The product will be evaluated employing a liquid to liquid matrix against *Mycobacterium bovis* BCG (TMC 1028). The product was exposed to the test organism in duplicate at four exposure times and quantified using membrane filtration. This study was conducted for research and development purposes; therefore, no product evaluation criteria has been established.

PROCEDURES:

TEST CULTURE:

A vial of frozen stock culture was removed from storage and thawed. An equal volume of buffered gelatin (BUGE) was added to the cell suspension and homogenized with a Teflon® tissue grinder for 1 minute while keeping the culture at 0-4°C in an ice bath. The homogenized cell suspension was diluted with saline Tween® 80 solution (ST80) to approximately 10^7 CFU/mL.

CHALLENGE TITRATION:

Tenfold serial dilutions of the culture were prepared in dilution blanks containing 9 mL of neutralizer broth (NEUB) through the 10^{-6} dilution. Three 1 mL aliquots of the appropriate dilutions were membrane filtered by first adding 10-20 mL physiological saline solution (PHSS) to the filter housing and then adding a 1 mL aliquot of the appropriate dilution. The filter was then rinsed with approximately 100 mL of PHSS. The filters were aseptically removed from the filter housing and placed onto 7H11 agar plates. The plates were incubated in a humidification chamber at $37 \pm 2^{\circ}\text{C}$ for 21 days.

POSITIVE CONTROL:

A tube containing 9 mL of ST80 was prepared and equilibrated to $20 \pm 0.5^{\circ}\text{C}$. At T 0, 1 mL of test organism was added to the tube (10^{-1} dilution). The sample was held for the longest time interval specified by the sponsor (60 minutes). Tenfold serial dilutions were prepared in dilution blanks containing 9 mL of NEUB through the 10^{-6} dilution. Three 1 mL aliquots of the appropriate dilutions were membrane filtered by first adding 10-20 mL PHSS to the filter housing and then adding a 1 mL aliquot of the appropriate dilution. The filter was rinsed with approximately 100 mL PHSS. The filters were aseptically removed from the filter housing and placed onto 7H11 agar plates. The plates were incubated in a humidification chamber at $37 \pm 2^{\circ}\text{C}$ for 21 days.

TEST PROCEDURE:

Two 25 x 150 mm tubes containing 9 mL of the test sample were equilibrated to $20 \pm 0.5^{\circ}\text{C}$ in a waterbath. To each tube containing the germicide, 1 mL of test organism was added. The tube was mixed by swirling and placed back into the waterbath. At 15, 30, 45, and 60 minutes, 1.0 mL aliquots of the disinfectant-cell suspension were transferred to 9 mL of NEUB and mixed thoroughly. Tenfold serial dilutions were prepared in dilution blanks containing 9 mL of NEUB through the 10^{-6} dilution. Three 1 mL aliquots of the appropriate dilutions were membrane filtered by first adding 10-20 mL PHSS to the filter housing and then adding a 1 mL aliquot of the appropriate dilution. The filter was rinsed with approximately 100 mL PHSS. The filters were aseptically removed from the filter housing and placed onto 7H11 agar plates. The plates were incubated in a humidification chamber at $37 \pm 2^{\circ}\text{C}$ for 21 days.

PHENOL CONTROL:

To demonstrate minimum culture viability and resistance, the culture was tested against a 0.8% phenol solution. A 1 mL aliquot of test organism was placed into 9 mL of the phenol solution equilibrated to $25 \pm 0.5^{\circ}\text{C}$ and incubated for 20 minutes. After the exposure period, 1 mL from the

phenol/organism solution was removed and added to 9 mL of NEUB. Tenfold serial dilutions were prepared in dilution blanks containing 9 mL of NEUB through the 10^{-6} dilution. Three 1 mL aliquots of the appropriate dilutions were membrane filtered by first adding 10-20 mL PHSS to the filter housing and then adding a 1 mL aliquot of the appropriate dilution. The filter was rinsed with approximately 100 mL PHSS. The filters were aseptically removed from the filter housing and placed onto 7H11 agar plates. The plates were incubated in a humidification chamber at $37 \pm 2^{\circ}\text{C}$ for 21 days.

NEUTRALIZATION VERIFICATION

A 1 mL aliquot of the disinfectant was added into 8 mL of NEUB. The disinfectant/neutralizer broth was allowed to equilibrate to the same temperature as the test samples. One mL of test organism was added to the mixture and mixed thoroughly. Incubation was continued for the approximate time it would take to filter a sample. Additionally, a 1 mL aliquot of test organism was added to 9 mL of NEUB and mixed thoroughly (10^{-1} dilution). Tenfold serial dilutions of both tubes were prepared in dilution blanks containing 9 mL of NEUB through the 10^{-6} dilution. Three 1 mL aliquots of the appropriate dilutions were membrane filtered by first adding 10-20 mL PHSS to the filter housing and then adding a 1 mL aliquot of the appropriate dilution. The filter was rinsed with approximately 100 mL PHSS. The filters were aseptically removed from the filter housing and placed onto 7H11 agar plates. The plates were incubated in a humidification chamber at $37 \pm 2^{\circ}\text{C}$ for 21 days.

RESULTS:

The starting titer for the challenge culture was 4.7×10^7 CFU/mL. The positive control titer was 6.5×10^6 CFU/mL. Challenge and positive control results are summarized in Table 1.

The media used in this study effectively demonstrated neutralization with a 95.2% recovery in a disinfectant/neutralizer solution when compared to a media blank. Neutralization results are summarized in Table 7.

For the test plates, expected counts were underestimated and therefore the reported counts exhibit ">" to mark that the count is an estimation and that accurate counts are beyond the limit of detection for the dilutions plated. The estimated counts for all time points for both replicates can be found in Tables 2 and 3.

In calculating the log and percent reductions of the disinfectant against *M. bovis*, the estimated counts which have "greater than" counts resulted in "less than" log and percent reductions (<). Again, the purpose of this is to demonstrate that the results are an estimation and beyond the

accurate limit of detection for the dilutions plated. All reductions were calculated using the positive control as the initial starting titer of the organism. The results for log and percent reductions are summarized in Tables 4 and 5. As a measure of the resistance of the challenge culture, the phenol resistance of *M. bovis*, Table 6, showed a ~1.81 log reduction with 20 minutes of exposure to 0.8% phenol.

Shelli Baxter

Shelli Baxter, B.S. SM(NRM)
Technical Reviewer

Robert W. Pritchett

Robert W. Pritchett, B.S.
Reuse Study Director

17 May 2001
Study Completion Date

RWP\kdw

TABLE 1. Positive Control and Challenge Titer

PLATE	DILUTION		CFU/mL
	10 ⁻⁵	10 ⁻⁶	
Positive Control	58	1	6.5 x 10 ⁶
	67	11	
	70	6	
Challenge Titer	TNTC	44	4.7 x 10 ⁷
	TNTC	49	
	TNTC	N/A ^a	

TNTC = Too Numerous Too Count

^a The plate dried out during incubation. Colonies could not be counted.

TABLE 2. Kill Time Test Results
ASAP Colloidal Silver (10 ppm), Lot #0845

PLATE	DILUTION				CFU/mL
	REST	10 ⁻¹	10 ⁻²	10 ⁻³	
T15	N/A	N/A	TNTC	$>8.5 \times 10^3$	$>5.7 \times 10^6$
		N/A	TNTC	$>2.9 \times 10^3$	
		N/A	TNTC	N/A ^a	
T30	N/A	N/A	TNTC	$>3.8 \times 10^3$	$>3.9 \times 10^6$
		N/A	TNTC	$>4.5 \times 10^3$	
		N/A	TNTC	$>3.4 \times 10^3$	
T45	TNTC	$>2.3 \times 10^4$	N/A	N/A	$>1.8 \times 10^5$
		$>1.8 \times 10^4$	N/A	N/A	
		$>1.3 \times 10^4$	N/A	N/A	
T60	TNTC	$>1.8 \times 10^4$	N/A	N/A	$>1.8 \times 10^5$
		N/A ^b	N/A	N/A	
		N/A ^b	N/A	N/A	

TNTC = Too Numerous Too Count

^a The plate dried out during incubation. Colonies could not be counted.

^b The plate was overgrown with mold. Colonies could not be counted.

TABLE 3. Kill Time Test Results
ASAP Colloidal Silver (10 ppm), Lot #0845

PLATE	DILUTION				CFU/mL
	REST	10 ⁻¹	10 ⁻²	10 ⁻³	
T15	NA	N/A	TNTC	>3.5 x 10 ³	>3.8 x 10 ⁶
		N/A	TNTC	>3.7 x 10 ³	
		N/A	TNTC	>4.3 x 10 ³	
T30	NA	N/A	TNTC	N/A ^b	>4.1 x 10 ⁶
		N/A	TNTC	>3.9 x 10 ³	
		N/A	TNTC	>4.3 x 10 ³	
T45	TNTC	>1.4 x 10 ⁴	N/A	N/A	>1.8 x 10 ⁵
		>2.1 x 10 ⁴	N/A	N/A	
		N/A ^c	N/A	N/A	
T60	TNTC	>1.9 x 10 ⁴	N/A	N/A	>1.9 x 10 ⁵
		N/A ^b	N/A	N/A	
		N/A ^b	N/A	N/A	

TNTC = Too Numerous Too Count

^a The plate dried out during incubation. Colonies could not be counted.

^b The plate was overgrown with mold. Colonies could not be counted.

TABLE 4. Average Log and Percent Reduction
ASAP Colloidal Silver (10 ppm), Lot #0845

REPLICATE 1

EXPOSURE TIME	LOG REDUCTION	PERCENT REDUCTION
15 minutes	<0.12	<12.3%
30 minutes	<0.22	<40.0%
45 minutes	<1.57	<97.2%
60 minutes	<1.56	<97.2%

TABLE 5. Average Log and Percent Reduction
ASAP Colloidal Silver (10 ppm), Lot #0845

REPLICATE 2

EXPOSURE TIME	LOG REDUCTION	PERCENT REDUCTION
15 minutes	<0.26	<44.6%
30 minutes	<0.20	<36.9%
45 minutes	<1.58	<97.3%
60 minutes	<1.53	<97.1%

TABLE 6. Phenol Resistance

PLATE	DILUTION		CFU/mL
	10^{-5}	10^{-6}	
Phenol	5	0	$\sim 5.7 \times 10^5$
	7	0	
	5	0	
Phenol Titer	TNTC	44	3.7×10^7
	TNTC	32	
	TNTC	36	

REDUCTION: $\sim 1.81 \log_{10}$

TNTC = Too Numerous Too Count

TABLE 7. Neutralization

PLATE	DILUTION		CFU/mL
	10^{-5}	10^{-6}	
Neutralization	TNTC	53	5.9×10^7
	TNTC	67	
	TNTC	56	
Neutralization Titer	TNTC	67	6.2×10^7
	TNTC	72	
	TNTC	48	

RECOVERY: 95.2%

TNTC = Too Numerous Too Count

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Attorney Docket No. 40056-0002

EXHIBIT 5

6/3/2003

SMALL BUSINESS
HOMELAND



SECURITY
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